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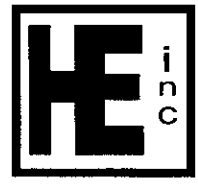

Harod Enterprises

FEB 22

Personal and Patient Care Products™

4052 Indian Creek Road • Martinez, Georgia 30907 • Phone (706) 228-5165 • Fax (706) 228-5095

510(k) Summary

As required by Section 807.92(c)

Revised For 510(k) Number K073576

The submitter and owner of the 510(k) is HE, Inc. whose contact information is in the above letterhead. The preparer and contact person during the review process is Norris R. Harod, President of HE, Inc.

This is a Traditional 510(k) submission for a Substantially Equivalent device.

- Common name: Neurological Pattie and/or Neurosponges
- Trade name: Neuro Patties and/or Neurosponges
- Classification: Name: Neurosurgical Paddie
  Class II Product code HBA Review panel Neurology
  Performance Standards NONE issued under Regulation # 882.4700

HE, Inc. and its contract manufacturer have been making the exact same product using the same material suppliers and a 510(k) license from McNeil Healthcare since 2005, but now we need our own 510(k). HE, Inc.'s device has the same intended use **and** identical technological characteristics as the predicate Neurological Sponges made by McNeil Healthcare, Inc. under K935883 and product codes 20501, 20502, 20504, 20505, 20506, and 20507.

A copy of the letter from McNeil Healthcare authorizing the use of their approved Premarket notification K935883 by HE, Inc. and our contract packager is attached. The letter is dated July 16, 2006 and establishes a trail that we are using the same biocompatible materials as our predicate McNeil Healthcare device under K935883. The letter also establishes that we will still be using the same contract packager (Bahia de Palomas), equipment, process and location to make the product as listed in our 510(k) Number K073536 if granted.

Neurosurgical Paddies are used to keep exposed tissue from drying out or to absorb excess fluids and to protect the tissue from trauma during surgery. They are manufactured from either cotton or viscose fibers cut into rectangular pads of various sizes with a suture string attached for ease in count verification and with an x-ray detectable marker sewn to it as an extra precaution. The paddies are normally packaged 10 per count card of a single size and may be sterilized for end use or sold non sterile for kit packers. They are single use items that can be ETO sterilized twice or E-beam sterilized once.

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HE, Inc.'s product will be made from cotton and/or or rayon in sizes and shapes similar to the predicate devices as they have been since 2005 under a 510(k) license. The most commonly used sizes are ½" x ½', ½' x 1", ½" x 3", 1" x 1" and 1" x 3". They will be contract packaged at the same FDA registered facility used in 2007 and ETO sterilized in the cycle and released by the criteria revalidated at our contract sterilizer during 2007. The only thing that will change is that this will be done under HE, Inc.'s 510(k) if granted.

Neurosurgical Paddies have been in use by surgeons since 1979 and are considered a prescription device due to their specialty use. Almost all labeling simply contains the product catalog number, name, size, material used, quantity, and "Rx Only" and "sterile if unopened, undamaged" statements. HE, Inc.'s labeling will contain these same items and/or whatever else may be specified by a relabeler customer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 22 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Harod Enterprises, Inc.
% Mr. Norris R. Harod
President
4052 Indian Creek Road
Martinez, Georgia 30907

Re: K073576
Trade/Device Name: Neuro Sponge and Neuro Pattie
Regulation Number: 21 CFR 882.4700
Regulation Name: Neurosurgical paddie.
Regulatory Class: II
Product Code: HBA
Dated: December 17, 2007
Received: December 19, 2007

Dear Mr. Harod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

HE, Inc. Traditional 510(k) Submission
Substantial Equivalence
For HBA Neurosurgical Paddies

HE, Inc. 510 (k) Number K073576

Device Name: Neuro Sponge and Neuro Pattie

Indications For Use: The neurological sponge is a cotton or rayon pattie used to keep exposed tissue from drying out during surgery. It is used to absorb excess fluids and to protect the tissue from trauma during surgery. It is also used to assist in the gentle suction of fluids.

Prescription Use: YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Millerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073576